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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,797	05/11/2001	Steven M. Ruben	PZ003P2	5177

22195 7590 12/23/2003

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EXAMINER	
ROBINSON, HOPE A	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 12/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/852,797	RUBEN ET AL.	
	Examiner	Art Unit	
	Hope A. Robinson	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,11,13,17-20 and 22-65* is/are pending in the application.

4a) Of the above claim(s) *1,13 and 17-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *11 and 22-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's election with traverse of Group II (claims 11-12 and 16 is acknowledged.

2. The traversal is on the ground(s) that the claims not be restricted and all claims are examined. Applicant states that even where patentably distinct inventions appear in a single application, restriction remains improper unless the examiner can show that the search and examination of these groups would entail a serious burden. Applicant further state that a search of the polynucleotide claims would provide useful information for examining claims directed to polynucleotides, the polypeptides and the corresponding methods of use.

Applicant's arguments have been fully considered but are not persuasive. Applicant is reminded that each application can only consist of one invention, therefore, if groups are patentably distinct then they must be filed separately. Although the DNA and protein are related to each other, they are separate and distinct. Each product has acquired a separate status in the art which adds burden to the search. Furthermore, each product has a different structure, function and mode of operation. Although the DNA can be used to produce the protein, the DNA can also be used in a materially different process such as a hybridization assay. The same is true of the protein since the protein can be used to produce the antibodies, however, the protein can also be used as a diagnostic. For all these reasons the Restriction Requirement was made and is proper. With respect to the methods, as the products can be used in a materially different process, restriction of these groups is proper. The arguments made by applicant have been addressed therefore the Restriction Requirement is maintained and is final.

3. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process

Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition

against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claim Disposition

Claims 2-10, 12, 14-16 and 21 have been canceled. Claims 24-65 have been added. Claim 17 has been amended. Claims 1, 11, 13, 17-20 and 22-65 are pending. Claims 11 and 22-65 are under examination.

Claim Disposition

4. Claims 2-20, 12, 14-16 and 21 have been canceled. Claims 24-65 have been added. Claim 17 has been amended. Claims 1, 11, 13, 17-20 and 22-65 are pending. Claims 11 and 22-65 are under examination.

Information Disclosure Statement

5. The information disclosure statement filed on October 20, 2003 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP 609 because the items listed on the information disclosure statement are missing from the application. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. A line has been drawn through the following items on the information disclosure statement: A through J.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 11 and 22-65 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claimed invention relates to an isolated protein contained in SEQ ID NO: 76 encoded by HTEEB42 cDNA contained in ATCC Deposit No. 97922. The specification on page 4 makes referral to the deposit of the sequence contained in ATCC Deposit No. 97922, however, this is insufficient assurance that all of the conditions of 37 CFR 1.801-1.809 have been met, because the specification does not indicate whether the sequence of the invention contained in ATCC Deposit No. 97922 is known and publicly available or can be reproducibly isolated. Without publicly available deposit information one skilled in the art could not be assured of the ability to practice the invention as claimed. It is noted that applicant made the deposits under the Budapest Treaty (see page 4), however, the specification need to be amended to disclose the date of the deposit and the public availability of the deposit. Amendment of the specification to disclose the date of the deposit and the complete name and address of the depository is required. For further information concerning deposit practice, applicants attention is directed to *In re Lundak* 773 F 2d 1216 227 USPQ CAFC and 37 CFR 1.801-1.809.

In addition, claim 11 recites "polypeptide fragments having biological activity", see for example claim 11. However, the specification is absent data on the claimed protein or its fragments affecting testicular cancer as a treatment. Note also that the claims are directed to a polypeptide with an unknown biological activity and there is no demonstration in the instant specification of fragments retaining the asserted utility disclosed on. The claims are also directed to fragments possessing 90% and 95% sequence identity to the claimed sequences without the recitation of functional language to demonstrate a measurable end point. The claims must recite a specific, measurable activity such that one can recognize a polypeptide as claimed, or a fragment thereof. Therefore, absent exemplification or direction/guidance of the claimed product as a medicament it would require undue experimentation to be able to practice the invention and a skilled artisan would not know if a polypeptide that is in possession of another, and having at least 95% identity to SEQ ID NO: 76, for example, falls within the description of the polypeptide as claimed. There is no function associated with polynucleotides encoding polypeptides having at least 95% or 90% identity to SEQ ID NO: 76, biological activity associated with fragments, allelic variants or homologs. Therefore, the claims must recite a specific, measurable activity such that one can recognize a polypeptide as that claimed or fragment thereof.

In view of the foregoing the specification lacks adequate written description to demonstrate applicant was in possession of the claimed invention.

7. Claims 11 and 22-65 are rejected under 35 U.S.C. 112 first paragraph, because the specification, while being enabling for the specific sequences (see for example, SEQ ID NO: 76),

does not reasonably provide enablement for fragments of the claimed sequence having an undisclosed biological activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. These factors include, but are not limited to: Quantity of Experimentation Necessary; Amount of direction or guidance presented; Presence or absence of working examples; Nature of the Invention; State of the prior art and Relative skill of those in the art; Predictability or unpredictability of the art and Breadth of the claims. These factors will be addressed below.

The claimed invention is directed to polynucleotides and the encoded polypeptide (see page 2 of the specification). Further, the specification on pages 49+ asserts that the polynucleotides and polypeptides corresponding to gene No. 25 can be used as reagents for differential identification of the tissue (s) or cell type (s) present in a biological sample and for diagnosis of diseases and conditions which include but are not limited to, diseases related to the testes, lung, tonsils, placenta and tumors. It is further stated that this gene is useful in the treatment of male infertility and/or impotence and the protein is believed to be useful in treatment of testicular cancer. However, the specification does not disclose any particular conditions wherein there is a deficiency, overproduction or altered form of the claimed polypeptides which would result in a specific disease or disorder to be treated with the claimed product. Significant further experimentation would be required of the skilled artisan to identify

individuals who would benefit from such a drug, and then to determine a best course of treatment.

It is further stated that the polypeptides and antibodies directed to these polypeptides are useful in providing immunological probes for differential identification of the tissues (s) or cell type (s). However, this asserted use is not demonstrated in the specification. The asserted use of probes is not specific and the specification provides no indicia of the claimed polypeptide and polynucleotide in association with infertility or testicular cancer via in vitro or in vivo studies. In addition, no working examples are provided to support the asserted use. Therefore, the specification at the time the application was filed, would not have taught one skilled in the art how to make and use the full scope of the claimed invention without undue experimentation to be enabling.

In addition, the specification does not provide sufficient guidance/direction regarding the deposit of the claimed sequence at ATCC. Therefore, in view of the foregoing, absent data or exemplification of the claimed use the specification is not enabled for the full scope of the claims. The invention is complex and since there's no analogous art, at the time of the invention a high level of skill is required. As insufficient guidance has been given regarding the deposit of the claimed sequence one skilled in the art would not be able to practice the claimed invention commensurate in scope with the claims. The breadth of the claims are very broad and encompass an unspecified amount of variants which are not adequately described or demonstrated in the specification as there is no detail as to where in the sequence the variation will occur or if function will be retained (see for example claims 1 and 36 reciting 90% and 95% identity to the claimed sequence).

Thus, for all these reasons, the specification is not considered to be enabling for one skilled in the art to make and use the claimed invention commensurate in scope with the claims.

Conclusion

8. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope Robinson whose telephone number is (703) 308-6231. The examiner can normally be reached on Monday-Friday from 9.00 am to 5.30 pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S.F. Low, can be reached at (703) 308-2923.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-4242. Please affix the examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Hope Robinson, MS

Patent Examiner

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER